

REMARKS

Claims 1-21 were pending in the subject application.

Claims 8-10 and 14 stand withdrawn by the Examiner.

Claims 1, 5, 6, 11, 14 and 15 are amended.

Claim 21 is canceled without prejudice or disclaimer of subject matter.

Accordingly, claims 1-20 are pending in the subject application.

The claims are amended to more clearly define the subject matter of the present invention. More specifically, the claims are amended to incorporate the subject matter of claim 21 into each of the independent claims 1, 11 and 15. No new matter is added.

The specification is amended to specifically describe the genes of the present invention, including a sequence listing of each of these genes and the proteins which they encode. Support for this amendment may be found in the original specification, at paragraphs [0072] and [0074], wherein genes IFI16, h19, RCC1, and hox2 are listed as genes useful in the present invention. Moreover, claim 21, as originally filed, lists the genes by their NCBI accession numbers, S75415 (IFI16), M32053 (h19), and X16665 (hox2). Claim 21 listed a fourth gene, D00597, however, this listing contains a typographical error, and should be D00591 (RCC1). Support for the finding of a typographical error may be found, as noted above, in paragraphs [0072] and [0074] of the originally filed specification, which lists RCC1 as a gene useful in the present invention as being involved in the regulation of cell proliferation. No new matter is added.

Applicant requests reconsideration of the pending claims in light of the above claim amendments taken along with the following remarks.

Election / Restriction

Applicant affirms the election, with traverse, of group I and species S75415. Claims 1-7, 11-13 and 15-20 are drawn to the elected group and species. Applicant notes, as the Examiner states at paragraph 3 of the office action, that claims 1-6, 11-13 and 15-21 link inventions I and II. Upon allowance of the linking claims, Applicant requests withdrawal of the restriction requirement as to the linked inventions and examination of Groups I and II on the merits.

Applicant respectfully requests reconsideration and withdrawal of the restriction requirement with respect to groups III and IV. Where the inventions are related as disclosed but are not distinct as claimed, restriction is never proper. MPEP § 806(C). In the present case, group III is drawn to diagnostic kits for carrying out the method of claim 1. Thus, the inventions of groups I and III are not independent (i.e., no disclosed relation therebetween). Further, group IV is drawn to a marker that is an antibody specific for at least one of the four genes predictive of the ability to respond to a tumor treatment. Thus, the inventions of groups I and IV are not independent. Therefore, to maintain restriction between group I with either of groups III or IV, Applicant requests the Examiner to make, of record, the statement that the inventions of groups I, III and IV are patentably distinct. Should the Examiner find these inventions are not patentably distinct, Applicant respectfully submits the restriction is improper and must be withdrawn.

Applicant notes, as the Examiner states at paragraph 6 of the office action, that upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.

Claim Rejections - 35 USC § 112

The Examiner rejects claims 1-7, 11-13 and 15-21 under 35 USC § 112, second paragraph, as being indefinite. More specifically, the Examiner raises issue with claims 1, 11, 15 and 21, as discussed in more detail below.

The Examiner rejects claim 1 under 35 USC § 112, second paragraph, because the phrase "the genes predictive for said treatment" lacks antecedent basis. Applicant thanks the Examiner for her careful consideration of the claims. Applicant has amended claim 1 to correct the issue of antecedent basis with respect to the phrase, "the genes predictive for said treatment." As such, Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 1 as being indefinite under 35 USC § 112, second paragraph.

The Examiner rejects claim 11 under 35 USC § 112, second paragraph, because it recites a claim to a method without a definition of how identification of a gene expression profile allows one to determine if cells or tissues will be sensitive or resistant to tumor treatment. Applicant has amended method claim 11 to include a step of determining whether the cells or tissues have present the gene expression profile, wherein its presence is indicative of the availability of cells or tissues to be sensitive or resistant to tumor treatment. For this reason, Applicant respectfully requests

reconsideration and withdrawal of the rejection of claim 11 as being indefinite under 35 USC § 112, second paragraph.

The Examiner rejects claim 15 under 35 USC § 112, second paragraph, because it is drawn to determining the presence or absence of expression of "a gene", wherein claim 21, which is dependent upon claim 15, is drawn to a method wherein the gene is selected from a group of four genes. While not acquiescing to the merits of the rejection, Applicant has amended claim 15 to include "at least one gene", wherein the at least one gene is selected from the four genes of claim 21. For this reason, Applicant respectfully requests reconsideration and withdrawal of the rejection of claim 15 as being indefinite under 35 USC § 112, second paragraph.

Finally, the Examiner rejects claim 21 under 35 USC § 112, second paragraph, because it recites terms that appear to be the names or designations of genes, without a definition of the structures that correspond to the names or designations. Applicant respectfully submits that one having ordinary skill in the art would recognize the designations of claim 21 as NCBI accession numbers corresponding to specific genes. As discussed above, claim 21 contains a typographical error, wherein gene D00597 should be D00591. Support for this finding may be found, for example, at paragraphs [0072] and [0074] of the specification, wherein four specific genes are listed as being involved in the regulation of cell proliferation. Three of these four genes correspond to three of the genes of claim 21. The fourth (RCC1, D00591) corresponds to D00597 recited (as a typographical error) in claim 21. Applicant has supplied a sequence listing corresponding to the four genes and the proteins they encode as part of the instant amendment. For this reason, as well as for the fact that claim 21 is canceled, Applicant

respectfully requests reconsideration and withdrawal of the rejection of claim 21 as being indefinite under 35 USC § 112, second paragraph.

Claims 1-7 and 15-21 stand rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. It appears that the Examiner rejects the claims as not adequately providing written description for the specific genes predictive for treatment. Moreover, it appears that the Examiner further rejects the claims as not providing an adequate written description of the genes S75415, M32053, X16665 and D00597 (D00591, as is typographically correct, see the discussions above).

Applicant has amended each of the independent claims to specifically identify four genes (or proteins) that are useful in the present invention. These four genes, as discussed above, are identified, for example, at paragraphs [0072] and [0074] of the originally filed specification. Applicant has, in the instant amendment, provided a sequence listing corresponding to these four genes and the proteins which they encode.

For the above reasons, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1-7 and 15-21 under 35 USC § 112, first paragraph, as lacking adequate written description.

Claim Rejections – 35 USC § 102

The Examiner rejects claims 1, 2, 4-7, 11-13, 15, 17 and 19-21 under 35 USC § 102(e) as being anticipated by Silverman (US 6,331,396). The Examiner urges that

Silverman teaches methods for establishing patient sensitivity to IFN- α by measuring the mRNA expression of genes.

Applicant respectfully submits that Silverman neither teaches nor fairly suggests using any of the four specific genes/proteins recited in the instant claims, as amended. For these reasons, it is Applicant's position that claims 1, 2, 4-7, 11-13, 15, 17 and 19-21 are neither anticipated nor rendered obvious by Silverman. Reconsideration and withdrawal of the rejection under 35 USC § 102(e) is respectfully requested.

The Examiner rejects claims 1, 2, 6, 7 and 11 under 35 USC § 102(b) as being anticipated by Johnston (Cancer Res., 55:1407-12, 1995). The Examiner urges that Johnston teaches a method for assessing patient responsiveness to 5-fluorouracil in human colorectal or gastric cancer patients, comprising measuring mRNA levels expressed by the thymidylate synthase gene. Therefore, the Examiner concludes, Johnston teaches the methods of the instant invention.

Applicant respectfully submits that Johnston neither teaches nor fairly suggests using any of the four specific genes/proteins recited in the instant claims, as amended. For these reasons, it is Applicant's position that claims 1, 2, 6, 7 and 11 are neither anticipated nor rendered obvious by Johnston. Reconsideration and withdrawal of the rejection under 35 USC § 102(b) is respectfully requested.

The Examiner rejects claims 1, 2, 4-7, 11-13, 15, 17, 19 and 20 under 35 USC § 102(a) as being anticipated by Celis (FEBS Letters, 480: 2-16, 2000). The Examiner urges that Celis teaches gene expression profiling using either cell lines or tissue biopsies for the purpose of predicting treatment outcome, comprising the use of DNA

microarrays. Therefore, the Examiner concludes, Celis teaches the methods of the instant invention.

Applicant respectfully submits that Celis neither teaches nor fairly suggests using any of the four specific genes/proteins recited in the instant claims, as amended. For these reasons, it is Applicant's position that claims 1, 2, 4-7, 11-13, 15, 17, 19 and 20 are neither anticipated nor rendered obvious by Celis. Reconsideration and withdrawal of the rejection under 35 USC § 102(a) is respectfully requested.

The Examiner rejects claims 1-3, 6, 7 and 11-13 under 35 USC § 102(b) as being anticipated by Scherf (Nature Genetics, 24:236-44, 2000). The Examiner urges that Scherf teaches detecting sensitivity to therapy in melanoma cell lines. Therefore, the Examiner concludes, Scherf teaches the methods of the instant invention.

Applicant respectfully submits that Scherf neither teaches nor fairly suggests using any of the four specific genes/proteins recited in the instant claims, as amended. For these reasons, it is Applicant's position that claims 1-3, 6, 7 and 11-13 are neither anticipated nor rendered obvious by Scherf. Reconsideration and withdrawal of the rejection under 35 USC § 102(b) is respectfully requested.

The Examiner rejects claims 11-13 under 35 USC § 102(b) as being anticipated by Der (Proc. Natl. Acad. Sci., 95:15623-28, 1998). The Examiner urges that Der teaches methods comprising the identification of gene expression profiles in HT1080 cell lines comprising the use of oligonucleotide probes. Therefore, the Examiner concludes, Der teaches the methods of the instant invention.

Serial No. 09/931,733
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Applicant respectfully submits that Der neither teaches nor fairly suggests using any of the four specific genes/proteins recited in the instant claims. For these reasons, it is Applicant's position that claims 11-13 are neither anticipated nor rendered obvious by Der. Reconsideration and withdrawal of the rejection under 35 USC § 102(b) is respectfully requested.

Conclusion

In summary, Applicant respectfully submits that the instant application is in condition for allowance. Early notice to that end is earnestly solicited.

If a telephone conference would be of assistance in furthering prosecution of the subject application, Applicant requests that the undersigned be contacted at the number below.

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No further fee is required in connection with the filing of this Amendment. If any additional fees are deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account No. 08-2525.

Respectfully submitted,



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Enclosed : Sequence listing – paper copy
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